REMARKS

The application has been amended to overcome the examiner's objections and rejections.

Claims 1-4 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polydextrose as the polyion and nitros-metyl-urea as a chemotherapeutic agent, does not reasonably provide enablement for all polyion polymers and to all the wide variety of chemotherapeutic drugs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This is scope of enablement which should not require undue experimentation.

The factors to be considered in determining whether undue experimentation is required were seen to include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The examiner cited a sufficient number of the factors considered to form a prima facie case. A) The nature of the invention: Claim 1 was drawn to a composition comprising polyion, chemotherapeutic drug and glucose solution.

B) The state of the prior art: The art recognizes a variety of t=chemotherapeutic agents. For example Wang and Li (The University of Texas System Board of Regents), adriarnycin, 5-fluorouracil(5-FU), etoposide (VP-16), camptothecin, actinomycin-D, mitomycin C, cisplatin and hydrogen peroxide are identified as chemotherapeutic agents (column 55, lines 57-61). Also, Pevarello et al. (US 6,114,365) identifies taxane, taxane

derivatives, CPT- 1 1, camptothecin derivatives, anthracycline glycosides, e.g., doxorubicin or epirubicin, etoposide, navelbine, vinblastine, carboplatin, cisplatin and as chemotherapeutic agents (column 17, lines 39-45). While all the above are known in the art, the claims are directed to one compound, nitros-metyl-urea without any mention of other chemotherapeutic agents in the specification. Prior art search for the term ccnitros-metyl-urea" or nitrous-methyl-urea" or nitrous-metyl-urea yields applicant's current work. Furthermore, polydextrose is the only polyion that the application mentions.

C) The amount of direction or guidance present -The specification only provides one polymer that is a polyion that is polydextrose and nitros-metyl-urea as the one chemotherapeutic drug.

D) The breadth of the claims: The claims are drawn compositions.

E) The quantity of experimentation needed would be an undue burden since there is inadequate guidance given to the skilled artisan for the reasons stated above.

F) The relative skill of those skilled in the art. Based on the unpredictable nature of the invention, one skilled in the art would not have envisioned practicing the invention without the exercise of undue experimentation and burden.

4. Claims 1-4 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is enablement.

It was seen that while the claims were directed to composition, the preamble of the claim stated the intended use of the composition as being selective for cancer cell chemotherapy. The support for a composition for treating any kind of cancer was lacking.

The claims were considered very broad and inclusive of a wide representation of cancers. It was considered that the amount of direction or guidance provided was lacking with an absence of working examples. There were seen to be no working examples to any specific cancer-type and the claimed composition. There is no one general mechanism of action for the treatment of cancers.

There was considered to be really no one composition that can be said to be effective for all cancers. It was seen that the specification did not provide structural and biochemical basis for the claimed composition for cancer cell selective chemotherapy having a priori expectations of success for using the claimed composition. Since it was considered that each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, it was seen that undue experimentation would be required to practice the invention as it is claimed in its current scope. It was seen that the specification provided inadequate guidance to do otherwise.

In consideration of each of factors above, it was considered apparent that there was undue experimentation required because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed was seen to be undue and the resultant outcome was seen to be not predictable.

Claims 1-3 were rejected under 35 U.S.C. 102(b) as being anticipated by Sahrada et al. (US 6,190,680).

Claims 2 and 3 were seen to recite the properties/characteristic/intended use of the composition so it was seen the claims were met.

Claim 1 was amended to claim: "A selective cancer chemotherapy delivery system using a compound of polyion polymers and a cancer specific chemotherapeutic drug with a glucose infusion so that the chemotherapy drug is only delivered to the cancer cell, the delivery system comprising:

a polyion polymer formed in a line from hundreds of units with different amounts of plus and minus radicals, the polyion polymer having a spatial form transformable between a globular closed form in a neutral and low alkaline solution and which polyion polymer takes an open line form in an acid environment;

a chemotherapeutic drug for killing a specific type of cancer cells combined with the polyion polymer to form a compound having a transformable spatial form responsive to the pH of a surrounding solution so that the chemotherapeutic drug is retained in an inactive form within the polyion polymer in the globular closed form and the chemotherapeutic drug is released in a free active form from the polyion polymer in the open line form;

a glucose solution for causing cancer cells to produce an acid environment, the glucose solution combined with the polyion polymer, the glucose solution and the compound of the polyion polymer and the chemotherapeutic drug being infused into a body containing cancer cells susceptible to treatment by the chemotherapeutic drug so that the glucose solution and the compound of the polyion polymer come in contact with the cancer cells, an acid environment when exposed to the glucose solution, so that the polyion polymer maintains a globular closed form in a neutral and low alkaline

environment of normal cells retaining the chemotherapeutic drug in an inactive form in the presence of normal cells and the polyion polymer transforms into the open line form in a glucose induced acid environment of the cancer cells releasing the chemotherapeutic drug in a free active form to attack and kill the cancer cells thereby selectively attacking the cancer cells and thereby providing a selective cancer chemotherapy delivery system using a compound of polyion polymers and a cancer specific chemotherapeutic drug with a glucose infusion so that the chemotherapy drug is only delivered to the cancer cells while leaving healthy tissue unharmed."

It is well known in the art that the two components of the compound as claimed in the amended claim 1 exist separately including "a polyion polymer formed in a line from hundreds of units with different amounts of plus and minus radicals, the polyion polymer having a spatial form transformable between a globular closed form in a neutral and low alkaline solution and which polyion polymer takes an open line form in an acid environment" and "a chemotherapeutic drug for killing a specific type of cancer cells." It as also well known that "a glucose solution...(causes)... cancer cells to produce an acid environment." Therefore, the amended claim 1 does not require undo experimentation to carry out the invention since a person skilled in the art would be familiar with each of the elements. Amending the claim so that the compound utilizes a chemotherapeutic drug for killing a specific type of cancer cells makes it clear that a person skilled in the art would be familiar with chemotherapeutic drugs and the types of cancer that each drug treats, so the person skilled in the art would not have to do undo experimentation to chose the right drug for treating the type of cancer being treated. A person skilled in the art would know a polyion polymer having the desired characteristics and would know how to make a

glucose solution having the desired characteristics. Therefore the two 112 rejections are seen to be overcome and claim 1 as amended is seen to be allowable based on overcoming the two 112 rejections.

Claim 1 as amended provides a novel "principe of selective cancer chemotherapy delivery system based on different PH in normal and tumor tissues and using a compound of polyion polymers and a cancer specific chemotherapeutic drug with a glucose infusion so that the chemotherapy drug is only delivered to the cancer cell" so that the novel "combination chemotherapeutic drug for killing a specific type of cancer cells combined with the polyion polymer to form a compound having a transformable spatial form responsive to the pH of a surrounding solution so that the chemotherapeutic drug is retained in an inactive form within the polyion polymer in the globular closed form and the chemotherapeutic drug is released in a free active form from the polyion polymer in the open line form." And further the novel combination of "the glucose solution and the compound of the polyion polymer and the chemotherapeutic drug being infused into a body containing cancer cells susceptible to treatment by the chemotherapeutic drug so that the glucose solution and the compound of the polyion polymer come in contact with the cancer cells, an acid environment when exposed to the glucose solution, so that the polyion polymer maintains a globular closed form in a neutral and low alkaline environment of normal cells retaining the chemotherapeutic drug in an inactive form in the presence of normal cells and the polyion polymer transforms into the open line form in a glucose induced acid environment of the cancer cells releasing the chemotherapeutic drug in a free active form to attack and kill the cancer cells thereby selectively attacking the cancer cells and thereby providing a selective

cancer chemotherapy delivery system using a compound of polyion polymers and a cancer specific chemotherapeutic drug with a glucose infusion so that the chemotherapy drug is only delivered to the cancer cells while leaving healthy tissue unharmed". Neither Sahrada et al. (US 6,190,680) nor any of the other prior art taken singly or together anticipate nor make it obvious to provide such a unique a selective cancer chemotherapy delivery system as found in the amended claim 1 of the present invention. Therefore the 102 rejection is seen to be overcome and amended claim 1 is now seen to be allowable.

Claims 2-4 and new claim 9 depend upon and further limit amended claim 1 now seen allowable, therefore claims 2-4 and 9 are also seen to be allowable.

In view of the above amendments and remarks, claims 1-4 and 9 are seen to be allowable. Reconsideration and allowance of claims 1-4 and 9 is respectfully requested.

A Petition to Revive an Abandoned Application Fee of $770 and the Petition to Revive are attached. No additional fee is seen to be due.

Respectfully submitted,

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